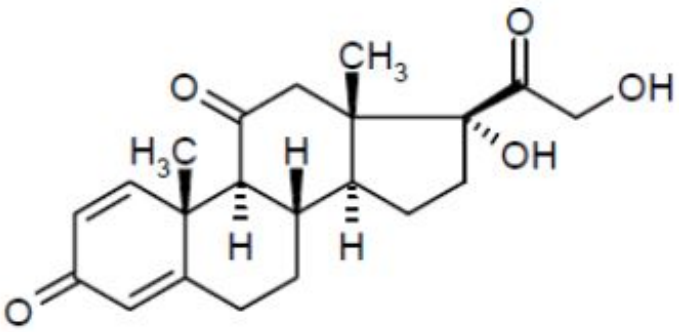
PREDNISONE- prednisone tablet
Amneal Pharmaceuticals NY LLC

PrediSONE Tablets, USP
(1 mg and 5 mg)
Rx only

DESCRIPTION

Prednisone, USP is a glucocorticoid. Glucocorticoids are adrenocortical steroids, both naturally occurring and synthetic, that are readily absorbed from the gastrointestinal tract. The chemical formula for prednisone is $C_{21}H_{26}O_5$. Chemically, it is 17,21-dihydroxypregna-1,4-diene- 3,11,20-trione and has the following structure:



Prednisone, USP is a white or practically white, crystalline powder and has a molecular weight of 358.4 g/mol. It melts at about 234°C. Prednisone, USP is very slightly soluble in water; slightly soluble in alcohol, chloroform, dioxane, and methanol. Prednisone tablets, USP contain 1 mg or 5 mg of prednisone, USP.

The inactive ingredients for prednisone tablets, USP include: lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate type A and stearic acid.

Meets USP Dissolution Test 2.

ACTIONS

Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency states. Their synthetic analogs, such as prednisone, are primarily used for their potent anti-inflammatory effects in disorders of many organ systems.

Glucocorticoids, such as prednisone, cause profound and varied metabolic effects. In addition, they modify the body’s immune response to diverse stimuli.

INDICATIONS

1. Endocrine Disorders

Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the first choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy mineralocorticoid supplementation is of particular importance)

Congenital adrenal hyperplasia

Nonsuppurative thyroiditis

Hypercalcemia associated with cancer

2. Rheumatic Disorders

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:

Psoriatic arthritis

Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)

Ankylosing spondylitis

Acute and subacute bursitis

Acute non-specific tenosynovitis

Acute gouty arthritis

Post-traumatic osteoarthritis

Synovitis of osteoarthritis

Epicondylitis

3. Collagen Diseases

During an exacerbation or as maintenance therapy in selected cases of:

Systemic lupus erythematosus

Acute rheumatic carditis

4. Dermatologic Diseases

Pemphigus

Bullous dermatitis herpetiformis

Severe erythema multiforme (Stevens-Johnson syndrome)

Exfoliative dermatitis

Mycosis fungoides

Severe psoriasis

Severe seborrheic dermatitis

5. Allergic States

Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment: Seasonal or perennial allergic rhinitis

Serum sickness

Bronchial asthma

Contact dermatitis

Atopic dermatitis

Drug hypersensitivity reactions

6. Ophthalmic Diseases

Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as:

Allergic conjunctivitis

Keratitis

Allergic corneal marginal ulcers

Herpes zoster ophthalmicus

Iritis and iridocyclitis

Chorioretinitis

Anterior segment inflammation

Diffuse posterior uveitis and choroiditis

Optic neuritis

Sympathetic ophthalmia.

7. Respiratory Diseases

Symptomatic sarcoidosis

Loeffler’s syndrome not manageable by other means

Berylliosis

Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy

Aspiration pneumonitis

8. Hematologic Disorders

Idiopathic thrombocytopenic purpura in adults

Secondary thrombocytopenia in adults

Acquired (autoimmune) hemolytic anemia

Erythroblastopenia (RBC anemia)

Congenital (erythroid) hypoplastic anemia

9. Neoplastic Diseases

For palliative management of:

Leukemias and lymphomas in adults

Acute leukemia of childhood

10. Edematous States

To induce a diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus.

11. Gastrointestinal Diseases

To tide the patient over a critical period of the disease in:

Ulcerative colitis

Regional enteritis

12. Miscellaneous

Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate anti-tuberculous chemotherapy

Trichinosis with neurologic or myocardial involvement

CONTRAINDICATIONS

Prednisone tablets are contraindicated in systemic fungal infections.

WARNINGS

In patients on corticosteroid therapy subjected to unusual stress, increased dosage of rapidly acting corticosteroids before, during, and after the stressful situation is indicated.

Corticosteroids may mask some signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localize infection when corticosteroids are used.

Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to fungi or viruses.

Usage in pregnancy

Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy, nursing mothers or women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards to the mother and embryo or fetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy, should be carefully observed for signs of hypoadrenalism.

Average and large doses of hydrocortisone or cortisone can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. These effects are less likely to occur with the synthetic derivatives except when used in large doses. Dietary salt restriction and potassium supplementation may be necessary. All corticosteroids increase calcium excretion.

While on corticosteroid therapy patients should not be vaccinated against smallpox. Other immunization procedures should not be undertaken in patients who are on corticosteroids, especially on high dose, because of possible hazards of neurological complications and a lack of antibody response.

Persons who are on drugs which suppress the immune system are more susceptible to infections than healthy individuals. Chickenpox and measles, for example, can have a more serious or even fatal course in non-immune children or adults on corticosteroids. In such children, or adults who have not had these diseases, particular care should be taken to avoid exposure. How the dose, route, and duration of corticosteroid administration affects the risk of developing a disseminated infection is not known. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If exposed to chickenpox, prophylaxis with varicella-zoster immune globulin (VZIG) may be indicated. If exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated (see the respective package inserts for complete VZIG and IG prescribing information). If chickenpox develops, treatment with antiviral agents may be considered. The use of prednisone tablets in active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for the management of the disease in conjunction with an appropriate anti-tuberculous regimen.

If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary as reactivation of the disease may occur. During prolonged corticosteroid therapy, these patients should receive chemoprophylaxis.

PRECAUTIONS

Information for Patients

Persons who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chickenpox or measles. Patients should also be advised that if they are exposed, medical advice should be sought without delay.

General

Drug-induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy; therefore, in any situation of stress occurring during that period, hormone therapy should be reinstituted. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently.

There is an enhanced effect of corticosteroids on patients with hypothyroidism and in those with cirrhosis.

Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible corneal perforation.

The lowest possible dose of corticosteroid should be used to control the condition under treatment, and when reduction in dosage is possible, the reduction should be gradual.

Psychic derangements may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression, to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies

may be aggravated by corticosteroids.

Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia.

Steroids should be used with caution in nonspecific ulcerative colitis, if there is a probability of impending perforation, abscess or other pyogenic infection; diverticulitis; fresh intestinal anastomoses; active or latent peptic ulcer; renal insufficiency; hyper tension; osteoporosis; and myasthenia gravis.

Growth and development of infants and children on prolonged corticosteroid therapy should be carefully observed.

ADVERSE REACTIONS

Fluid and Electrolyte Disturbances

Sodium retention

Fluid retention

Congestive heart failure in susceptible patients

Potassium loss

Hypokalemic alkalosis

Hypertension

Musculoskeletal

Muscle weakness

Steroid myopathy

Loss of muscle mass

Osteoporosis

Tendon rupture, particularly of the Achilles tendon

Vertebral compression fractures

Aseptic necrosis of femoral and humeral heads

Pathologic fracture of long bones

Gastrointestinal

Peptic ulcer with possible perforation and hemorrhage

Pancreatitis

Abdominal distention

Ulcerative esophagitis

Dermatologic

Impaired wound healing

Thin fragile skin

Petechiae and ecchymoses

Facial erythema

Increased sweating

May suppress reactions to skin tests

Neurological

Convulsions

Increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment

Vertigo

Headache

Endocrine

Menstrual irregularities

Development of Cushingoid state

Suppression of growth in children;

Secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness

Decreased carbohydrate tolerance

Manifestations of latent diabetes mellitus

Increased requirements for insulin or oral hypoglycemic agents in diabetics

Ophthalmic

Posterior subcapsular cataracts

Increased intraocular pressure

Glaucoma

Exophthalmos

Metabolic

Negative nitrogen balance due to protein catabolism.

Additional Reactions

Urticaria and other allergic, anaphylactic or hypersensitivity reactions

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Pharmaceuticals at 1-877-835-5472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

Dosage of prednisone tablets should be individualized according to the severity of the disease and the response of the patient. For infants and children, the recommended dosage should be governed by the same considerations rather than strict adherence to

the ratio indicated by age or body weight.

Hormone therapy is an adjunct to, and not a replacement for, conventional therapy.

Dosage should be decreased or discontinued gradually when the drug has been administered for more than a few days.

The severity, prognosis, expected duration of the disease, and the reaction of the patient to medication are primary factors in determining dosage.

If a period of spontaneous remission occurs in a chronic condition, treatment should be discontinued.

Blood pressure, body weight, routine laboratory studies, including two hour postprandial blood glucose and serum potassium, and a chest X-ray should be obtained at regular intervals during prolonged therapy. Upper GI X-rays are desirable in patients with known or suspected peptic ulcer disease.

The initial dosage of prednisone may vary from 5 mg to 60 mg per day, depending on the specific disease entity being treated. In situations of less severity lower doses will generally suffice, while in selected patients' higher initial doses may be required. The initial dosage should be maintained or adjusted until a satisfactory response is noted. If after a reasonable period of time there is a lack of satisfactory clinical response, prednisone should be discontinued, and the patient transferred to other appropriate therapy. **IT SHOULD BE EMPHASIZED THAT DOSAGE REQUIREMENTS ARE VARIABLE AND MUST BE INDIVIDUALIZED ON THE BASIS OF THE DISEASE UNDER TREATMENT AND THE RESPONSE OF THE PATIENT**. After a favorable response is noted, the proper maintenance dosage should be determined by decreasing the initial drug dosage in small decrements at appropriate time intervals until the lowest dosage which will maintain an adequate clinical response is reached. It should be kept in mind that constant monitoring is needed in regard to drug dosage. Included in the situations which may make dosage adjustments necessary are changes in clinical status secondary to remissions or exacerbations in the disease process, the patient's individual drug responsiveness, and the effect of patient exposure to stressful situations not directly related to the disease entity under treatment; in this latter situation it may be necessary to increase the dosage of prednisone for period of time consistent with the patient's condition. If after long-term therapy the drug is to be stopped, it is recommended that it be withdrawn gradually rather than abruptly.

HOW SUPPLIED

Prednisone Tablets USP, **1 mg** are supplied as white to off-white, round, biconvex, uncoated tablets, scored on one side and debossed with "A43" on the other side.

They are available as follows:
Bottles of 100 (with child-resistant closure): NDC 60219-1705-1

Prednisone Tablets USP, **5 mg** are supplied as white to off-white, round, biconvex, uncoated tablets, scored on one side and debossed with "I2" on the other side.

They are available as follows:
Bottles of 100 (with child-resistant closure): NDC 60219-1706-1
Bottles of 1000: NDC 60219-1706-7

Cartons of 100 (10 × 10 unit-dose tablets): NDC 60219-1706-3

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Dispense in a tight, child-resistant container as defined in the USP.
Protect from moisture.

Manufactured by:
Amneal Pharmaceuticals Pvt. Ltd.
Oral Solid Dosage Unit
Ahmedabad 382213, INDIA

Distributed by:
Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

Rev. 08-2021-02

PRINCIPAL DISPLAY PANEL

NDC 60219-1705-1
PredniSONE Tablets USP, 1 mg
100 Tablets
Bottle Label
Rx Only
Amneal Pharmaceuticals LLC

NDC 60219-1706-1
PredniSONE Tablets USP, 5 mg
100 Tablets
Bottle Label
Rx Only
Amneal Pharmaceuticals LLC

NDC 60219-1706-2
PredniSONE Tablets USP, 5 mg
10's Blister Label
Rx Only
Amneal Pharmaceuticals LLC

NDC 60219-1706-3
PredniSONE Tablets USP, 5 mg
100 Tablets [10 × 10] Unit-Dose Tablets
Carton Label

Rx Only
Amneal Pharmaceuticals LLC

PREDNISONE

prednisone tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60219-1705
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PREDNISONE (UNII: VB0R961HZT) (PREDNISONE - UNII:VB0R961HZT)	PREDNISONE	1 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (white to off-white)	**Score**	2 pieces
Shape	ROUND	**Size**	5mm
Flavor		**Imprint Code**	A43
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60219-1705-1	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213385	08/04/2021	

PREDNISONE

prednisone tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60219-1706
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PREDNISONE (UNII: VB0R961HZT) (PREDNISONE - UNII:VB0R961HZT)	PREDNISONE	5 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (white to off-white)	**Score**	2 pieces
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	I2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60219-1706-1	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2021	
2	NDC:60219-1706-7	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2021	
3	NDC:60219-1706-3	10 in 1 CARTON	08/04/2021	
3	NDC:60219-1706-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213385	08/04/2021	

Labeler - Amneal Pharmaceuticals NY LLC (123797875)

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